

REMARKS

Reconsideration of the above-identified Application is respectfully requested. This is an response to the final Office Action dated May 16, 2007, for purposes of establishing a record of telephonic interviews with the Examiner on June 14, 18, and 28, 2007.

Applicant is pleased that all rejections of the claims on the 35 U.S.C. § 103(a) has been withdrawn.

Claims 1-7, 9, 16 and 19, 20 and 22-27 and new claims 28-29 are pending in the Application. The Examiner is rejecting the claims under 35 U.S.C. § 112, first paragraph for failing to comply with the written description requirement. The Examiner believes that the claims contain subject matter not described in the specification, for example, including the phrase "the therapeutic agent is disbursed from the microchannels---for distribution to the skin." The Examiner believes that this matter is not supported in the original specification.

The Examiner is invited to refer to the following paragraphs of the published application:

[0036] As seen in FIG. 1, the composite sheet 10 of the present invention comprises a top or first side 20 showing a plurality of apertures or microchannels 30 in the first side 20. The microchannels 30 run from first aperture 32 on the top side 20 through a porous passage 34, as seen in FIGS. 2 and 3 to a second aperture 36, exiting the second side 40 of the composite sheet of the present invention.

[0037] "the microchannels 30 pass through a polymer enrobing material 50 which contacts the skin on the second side of the composite and encapsulates a flexible porous polymer foam material 60 that holds and releases a therapeutic agent 70.

[0041] FIG. 3 shows a composite sheet that has microchannels 30 filled with a therapeutic agent 70. The microchannels are filled completely so that the therapeutic agent 70 reaches the second aperture 36. The therapeutic agent may flow downward past the second aperture 36 to collect in bulge 72.

[0043] Further, a rigid polymer strip 90 may be applied to either side of the composite sheet, however, preferably it is applied on the second side 40 to cover the polymer liner 80 over aperture 32 and 36. The strip 90 may or may not have raised protrusions 92 to aid the blockage of the therapeutic agent 70 in the microchannels 30, preferably on the second side that contacts the skin of the patient. The strip 90 is removably attached from the first and second sides 20 and 40 prior to application of the composite sheet to the skin. The strip 90 is shown on second side 40 in FIGS. 3 and 4.

In addition, paragraphs [0047], [0048], [0052], and [0053] also provide support.

It is clear that the therapeutic agent can be added into the micro-channels for release onto the skin surface. However, the composite sheet provides another function. The composite sheet also delivers a therapeutic agent which is loaded into the microchannel, and passes into the flexible polymer foam material and then the polymer enrobing for release to the skin. The composite sheet has two methods of delivering the therapeutic agent, (1) the therapeutic agent may be released from the microchannel to the skin surface, and (2) the therapeutic agent may also be released from the microchannel into the flexible polymer foam material and polymer enrobing material for release into the skin surface. Support for the release of a therapeutic agent from the microchannel into the polymer foam and polymer enrobing agent is shown throughout the specification and specifically in many paragraphs of the published application ([0037], [0038], [0044], [0047], [0048], and [0053]).

The claims have been amended to clarify these embodiments. Claim 1 has been amended to show that the therapeutic agent is delivered from the micro-channels into the porous polymer foam material and the polymer enrobing material for release to the skin. This claim defines the structure of the composite sheet and an antecedent basis for delivering the therapeutic agent is found in the preamble of the claim. Claims 9 and 27 has been amended to include additional therapeutic agents that may be utilized in the composite sheet and method of the claimed invention. Support for these agents is found in paragraph [0047] of the published application. Claim 21 has been cancelled and rewritten as new claim 28 to show the release of the therapeutic agent from a plurality of microchannels to the skin. Method claim 22 has also been amended to delete the word “distributing” and insert the word “releasing” for a better characterization of the

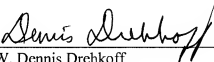
action of the claim. New claim 28 has been added to show the release time of the therapeutic agent.

Conclusion

It is respectfully submitted that the claims define patentable subject matter and meet the requirements of 35 U.S.C. § 112, first and second paragraphs. An early Notice of Allowance of the claims as presented is respectfully requested. The Commissioner is hereby authorized to charge any underpayment or credit any overpayment to Deposit Account No. 22-0259 or any payment in connection with this communication, including any fees for new claims that may be required. The Examiner is invited to contact the below listed attorney if the Examiner believes that a telephone conference will advance the prosecution of this application.

Respectfully submitted,

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